UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 05-1621

PHARMANETICS, INCORPORATED,

Plaintiff - Appellant,

versus

AVENTIS PHARMACEUTICALS, INCORPORATED, a/k/a Aventis Pharmaceuticals Products, Incorporated,

Defendant - Appellee.

Appeal from the United States District Court for the Eastern District of North Carolina, at Raleigh. Louise W. Flanagan, Chief District Judge. (CA-03-817-5)

Argued: March 15, 2006 Decided: May 31, 2006

Before WIDENER and WILLIAMS, Circuit Judges, and William L. OSTEEN, Senior United States District Judge for the Middle District of North Carolina, sitting by designation.

Affirmed by unpublished per curiam opinion.

ARGUED: Gregory Neil Stillman, HUNTON & WILLIAMS, Norfolk, Virginia, for Appellant. Nancy Karen Deming, TROUTMAN SANDERS, L.L.P., Atlanta, Georgia, for Appellee. **ON BRIEF:** Robert C. Van Arnam, HUNTON & WILLIAMS, Raleigh, North Carolina; Gary C. Messplay, HUNTON & WILLIAMS, Washington, D.C.; Brent L. VanNorman, HUNTON & WILLIAMS, Norfolk, Virginia, for Appellant. J. Donald Cowan, Jr., SMITH MOORE, L.L.P., Greensboro, North Carolina; John J. Dalton, William N. Withrow, Jr., Mark S. VanderBroek, TROUTMAN SANDERS, L.L.P., Atlanta, Georgia, for Appellee.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

PER CURIAM:

PharmaNetics, Inc. ("Appellant") brings this appeal challenging the district court's rulings in (1) striking its expert testimony and (2) granting summary judgment on its state law breach-of-contract and its Lanham Act claims, see 15 U.S.C. § 1051 et seq., in Aventis Pharmaceuticals, Inc.'s ("Appellee") favor. For the reasons stated below, this court affirms the district court's ruling.

I.

Appellant is a drug development company that in the late 1990's began developing a diagnostic test to quickly monitor the effects of certain types of anticoagulants (blood thinners). Doctors generally use anticoagulants in, among other areas, patients who have unstable angina, a condition where restricted blood flow to the heart can cause an increased risk of heart attack.[1] Patients with unstable angina can receive two levels of treatment. A first level, "medical management," involves administering various drugs,

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[1]A brief description is as follows:

> [A]ngina, whether stable or unstable, is a result of coronary artery disease (clogged arteries). Angina becomes unstable when the arteries become so occluded as to . . . restrict the blood flow to the heart [dangerously], posing a threat of plaque breakage or rupture [that] could cause a sudden stoppage of the blood flow to the heart.

Leddy v. Mississippi State Med. Ass'n, 7 F. Supp. 2d 819, 821 (S.D. Miss. 1998).

including anticoagulants. A second level, "invasive management," involves instruments that physically remove any blockages. Patients receive anticoagulants during invasive management to prevent fatal blood clots (when blood is too thick) or hemorrhaging (when blood is too thin). Doctors must know the anticoagulant's effect precisely during invasive management because too much or too little anticoagulant can lead to death during this drastic procedure. Diagnostic monitoring tests, which Appellant develops, seek to accomplish this goal.

Unstable angina may accompany other diseases, which can necessitate changing the monitoring requirements. One such disease combination is UA/NSTEMI.[2] UA/NSTEMI patients can receive medical management but may later transfer to invasive management, which many do. Some cardiologists prefer to monitor coagulation levels during this entire process, including during medical management.

Since the 1990's, Appellee, a pharmaceutical company, has marketed Lovenox as an anticoagulant that requires no routine monitoring of blood coagulation, with disclaimers that certain patients may require monitoring. Specifically, other warnings on

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[2]UA/NSTEMI means the patient has unstable angina and is at an increased risk for non-ST-segment elevation myocardial infarction, a specific type of heart attack. See Braunwald et al., Am. Coll. of Cardiology & Am. Heart Ass'n, ACC/AHA 2002 Guideline Update for the Management of Patients with Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction 4, 73-74 (2002), available at http://www.acc.org/clinical/guidelines/unstable/incorporated/UA_incorporated.pdf.

the package state anticoagulation monitoring is essential when doctors administer Lovenox with other drugs or to certain patient populations. The FDA, moreover, has approved Lovenox without monitoring for medical management but not invasive management. No quick-acting monitoring test existed for Lovenox initially.

The inability to monitor Lovenox's coagulation effects with sufficient quickness limited its use. During invasive management, doctors must know coagulation levels with quickness. Some doctors, furthermore, preferred to measure coagulation levels in UA/NSTEMI patients during all managements, which must occur with similar quickness. Thus, Lovenox was unsuitable for not only invasive treatments but also, in some doctors' opinions, medical management of UA/NSTEMI patients.

In August 2000, the parties entered into an agreement to co-develop and co-promote Enox, a test that would quickly monitor Lovenox's blood-clotting effects and expand Lovenox's market. After forming the agreement, Appellee allegedly delayed Enox's development by imposing unreasonable obligations and demands besides those in the agreement, including changing the required range for Enox's application. Appellant claims Appellee imposed these obligations to avoid its contractual obligations.

Appellee's alleged motivation for avoiding these obligations was that Appellee did not want Enox's development and promotion to harm its long-standing, no-monitoring promotion for certain

patients. During the post-contract-formation period, Appellee continued its long-standing marketing of Lovenox and, allegedly, even aimed it at invasive-management patients. The marketing included advertisements stating Lovenox (1) was therapeutic within one-half hour and from one dose and (2) required no routine coagulation monitoring. Appellant claims these advertisements were false under the Lanham Act since Appellee aimed its no-monitoring-based advertisements at consumers who, in some cases, required monitoring. These advertisements harmed Appellant through lost sales.

The parties continued Enox's development. After Enox's launch in January 2003, Appellant claims doctors reported Enox showing Lovenox overcoagulated some patients and undercoagulated others. Because Enox showed Lovenox unpredictably coagulated blood and, thus, needed close monitoring, Appellee then allegedly began distancing itself from Enox even more. Appellee stopped any sales and support given to Appellant, discarded promotional materials, and disparaged Enox as useless. Appellant claims these acts not only breached the agreement but also caused damages through lost present and future Enox sales.

Appellee argues that Appellant lost sales for various reasons other than its acts, including the medical community's resistance to Enox because of its cost and imprecision, Enox's limited utility, its lack of clinical-trial support, doctors' reluctance to change

when they were comfortable with using Lovenox without monitoring even in some UA/NSTEMI patients, low numbers of patients taking Lovenox during invasive management, hospitals' bureaucratic purchasing processes, and Enox's general difficulty in use.

To prove its lost sales damages, Appellant sought to introduce the testimony of Richard Troxel ("Troxel"). His testimony was Appellant's only evidence of damages. Prior to formulating his expert opinion, Troxel met with Appellant to get an overview of this lawsuit and Appellant's business. Appellant gave Troxel a myriad of requested documents, including both parties' sales projections for Enox. Troxel reviewed the documents and found both sales projections to be consistent. Troxel considered Appellee's five-year sales projections to be the most important piece of evidence. Troxel then proceeded to determine values for variables that would determine lost profits, including (1) estimating the number of Enox tests needed per patient, based on both parties' projections, (2) setting the price per test at $25.00, to which Appellee's expert agreed, (3) calculating the per-test profit (subtracting the test's manufacturing costs and any sales commissions), (4) adding a residual value to Appellant's total five-year net income based on similar industries, and (5) applying two discount rates to determine what the future earnings are presently worth. Appellant's expert proffered several damages estimates created under various assumptions. The district court excluded Troxel's report because

it was (1) too disconnected from this case's facts and (2) too speculative.

The district court ruled Appellant's damages model to be too disconnected for various reasons. For example, the report assumed that Appellee "[wa]s liable for all of the actions alleged in each of [Appellant's] claims, and . . . [it assumed] that [only Appellee's] actions caused" all of Appellant's losses, "rather than only those . . . [that] are reasonably inferred from the . . . record." (J.A. at 6737.) The district court, thus, held that Appellant calculated all possible losses and indiscriminately assessed all losses to Appellee. In examining this evidence as expert testimony under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), the district court held that the evidence failed to meet Daubert's standard for "fit." The evidence was simply not "sufficiently tied to the facts of the case." (J.A. at 6730 (quoting Daubert, 509 U.S. at 591).)

At the time of the court's ruling, Appellee was not liable under all claims, as the report assumed, because the district court had granted partial summary judgment. Also, the uncontested evidence showed that multiple sources caused or would cause lost sales. For example, the court noted that doctor resistance to switch to Enox, low populations of Lovenox patients, Appellee's conduct in telling its representatives not to promote Enox, and the FDA's limited approval of Enox all caused lost sales. A lump sum,

indiscriminately attributed to Appellee, was not sufficiently tied to the facts when the evidence showed various factors caused lost sales. Implicitly, the jury had no reasonable method to dissect the report and assess what acts may have caused particular losses. The evidence, thus, was too misleading to go before a jury as expert testimony because "too great an analytical gap [existed] between the data and the opinion proffered." (J.A. at 6731 (quoting General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).)

The district court then explained why Troxel's report was too speculative. Citing case law, the district court stated any damages report must have reasonable certainty. The court found Enox was a novel technology and determining future sales was not made on the basis of established past sales of this or similar technologies. Furthermore, maximizing Enox's potential relied on Appellee's full cooperation (which the agreement may or may not require), and Appellant faced reluctant consumers unwilling to switch from their current tests. Under these facts, Appellant's evidence was simply too speculative to be "expert testimony"—a moniker that could unfairly persuade a jury that the speculative evidence has much more certainty and precision than reality showed.

II.

A.

1.

Appellant first argues this court should reverse the district court's exclusion of Troxel's report. Appellant's reasons are various, including the argument that an opposing party's estimates of lost profits, upon which Troxel relied, are inherently reliable. Thus, because Troxel relied on Appellee's lost profits estimates, the evidence is almost automatically admissible. Appellant contends the district court also "impermissibly resolved the competing evidence when it labeled Troxel's acceptance of [Appellee's lost sales] projections as 'speculative' and 'not sufficiently tied to the facts of the case.'" (Appellant's Br. at 55.)

The district court noted that the report assumed (1) Appellee was liable on all causes of action and (2) multiple sources caused damages. Appellant argues that the report factored these issues into its calculations, and thus, the district court's reasoning on that point was flawed. According to Appellant, the district court impermissibly mandated that the evidence must exhaust all possible causes of lost sales because case law does not require an expert witness to eliminate all possible causes of injuries. Appellant further argues the district court ignored two important Lanham Act principles: (1) a wrongdoer should not profit from a Lanham Act violation and (2) the wrongdoer should bear the uncertain losses of

his conduct. Finally, Appellant contends the district court failed to conduct the required Daubert analysis. Appellant argues that (1) the district court had to delineate analysis on four factors for evaluating expert testimony that Appellant gleaned from case law, (2) the court evaluated Troxel's factual assumptions instead of his methodology, (3) Troxel's factual assumptions have support in the record, and (4) case law does not support striking Troxel's opinion.

2.

Federal Rule of Evidence 702 provides that

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

"Courts of appeals apply an abuse of discretion standard when reviewing a trial court's decision to admit or exclude expert testimony [under Rule 702]." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 200 (4th Cir. 2001). "A district court abuses its discretion if its conclusion is guided by erroneous legal principles or rests upon a clearly erroneous factual finding." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999) (citations omitted). This court

> is obligated "to consider the full record" as well as the reasons assigned by the [district] [c]ourt for its judgment, and to reverse the judgment below, if after

> such review, the appellate court "has a definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors."

Wilson v. Volkswagen of Am., Inc., 561 F.2d 494, 506 (4th Cir. 1977) (emphasis added) (quoting Finley v. Parvin/Dohrmann Co., 520 F.2d 386, 390 (2d Cir. 1975)).

Furthermore, "[t]he Supreme Court also has emphasized that 'the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.'" Cooper, 259 F.3d at 200 (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999)). No established procedure exists for Daubert analysis: "[T]he factors discussed in Daubert [for analyzing the testimony] were neither definitive, nor exhaustive. . . . [P]articular factors may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Id. at 199–200; accord Westberry, 178 F.3d at 261 ("In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved."). Finally, even though Federal Rule of Evidence 702 "liberalize[d] the introduction of relevant expert evidence," the district court must balance that

freedom with the persuasiveness of potentially misleading expert evidence. 178 F.3d at 261.

The district court ruled the expert evidence too misleading, because it was a lump sum, not sufficiently tied to Appellee's possible conduct, and too speculative, because the technology was novel. As to the first reason, the district court did not see divisible units of damages that a jury could reasonably assign to Appellee's possible wrongful conduct. Unless Appellant tailored the evidence to the facts, the district judge would not put the lump sum before a jury as expert evidence. "[G]iven the potential persuasiveness of expert testimony," Troxel's lump sum evidence "ha[d] a greater potential to mislead than to enlighten." Id. Even though part of the district court's rationale was that Appellee was not liable under all claims because it had granted partial summary judgment, a ruling whose substantive merits this court will not consider, the district court's rationales need not be applicable in full. Cf., e.g., United States v. White, 222 F.3d 363, 372 (7th Cir. 2000) (affirming a district court's evidentiary ruling for different reasons under the Federal Rules of Evidence). The district court's other rationales are sufficient to exclude the expert testimony because nothing appears to be clear error, under these facts, in ruling the lump sum losses to be too misleading when presented as expert testimony. Moreover, Appellant shows no clear error in ruling the new technology's lost sales to be too

speculative. Because Appellant does not show "a definite and firm conviction" of "clear error," Wilson, 561 F.2d at 506 (quoting Finley, 520 F.2d at 390), this court will affirm the ruling that excluded Troxel's proffered expert testimony.

B.

Appellant next argues that its Lanham Act claim involving Appellee's "therapeutic" claims had a presumption of harm and damages. Appellee advertised that Lovenox was therapeutic from one dose and in one-half hour, meaning Lovenox properly coagulated, without monitoring, a patient under those conditions. The district court found Appellee's therapeutic claims to be literally false, and Appellant further argues that Appellee intentionally deceived consumers with the advertisements. Appellant argues, under those two situations, damages are presumed. The district court rejected these presumptions because (1) Fourth Circuit precedent questions whether such presumptions apply, (2) any presumptions of harm exist only in injunction settings and not in money damages claims, and (3) the presumptions apply where a competitor's advertising misleads. This ruling will be affirmed, but through different analysis without comment on the district court's analysis.

Assuming that a presumed-damages standard would apply to this Lanham Act claim, damages are presumed only as to causation; the extent of money damages is a separate matter that must have

evidentiary support. See, e.g., Porous Media Corp. v. Pall Corp., 110 F.3d 1329, 1336 (8th Cir. 1997) (noting that a Lanham Act plaintiff, even when presumptions of harm apply, "still b[ears] the burden of proving an evidentiary basis to justify any monetary recovery"); PPX Enters., Inc. v. Audiofidelity Enters., Inc., 818 F.2d 266, 271–73 (2d Cir. 1987) ("[T]he quantum of damages, as distinguished from entitlement, must be demonstrated with specificity . . . ."). Thus, a Lanham Act plaintiff may not have to prove harm through, for example, consumer surveys, but that plaintiff must still prove the harm's financial extent. See 818 F.2d at 273 ("[T]o assist . . . in measuring damages, [a party] will, of course, be required to provide 'an evidentiary basis on which to rest such an award.'" (quoting Vuitton Et Fils, S.A. v. Crown Handbags, 492 F. Supp. 1071, 1077 (S.D.N.Y. 1979))).

C.

In affirming the evidentiary ruling and holding that Appellant must produce evidence of the extent of damages even if a presumption of harm applies, this court must affirm the grant of summary judgment on all claims because Appellant has no further evidence of damages.[3] Summary judgment is appropriate where an examination of

[3]The district court decided summary judgment through these and additional grounds. The court makes this decision without comment on the district court's analysis except to the extent it agrees with this opinion.

the pleadings, affidavits, and other proper discovery materials before the court demonstrates no genuine issue of material fact exists, thus entitling the moving party to judgment as a matter of law. Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986). The court must view the facts in the light most favorable to the nonmovant, drawing inferences favorable to that party if such inferences are reasonable. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

For a successful breach-of-contract claim for damages, a party must generally, among other things, produce evidence of damages. See, e.g., Restatement (Second) of Contracts § 346(2) (1981).[4] For a Lanham Act claim for money damages, as discussed above, a party must also generally produce some evidence of damages. See, e.g., Xoom, Inc. v. Imageline, Inc., 323 F.3d 279, 286 (4th Cir. 2003). After excluding Troxel's report, Appellant has no further evidence on damages. Summary judgment, thus, is appropriate because a fact finder could not award relief without such evidence.

[4]Though the contract has a choice-of-law clause, the court finds no conflict in the possibly applicable laws and thus no reason to decide what substantive law applies in determining this basic and generally applicable contract principle.

III.

For the reasons stated above, the district court's evidentiary ruling is affirmed. With this ruling, Appellant has no further evidence of damages, and thus, summary judgment on all claims is

AFFIRMED.